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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,059	02/19/2002	Harry Wotton III	2839.1001-003	5944
21005 7590 07/26/2007 HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			EXAMINER DAWSON, GLENN K	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 07/26/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/079,059

Applicant(s)

WOTTON, HARRY

Examiner

Glenn K. Dawson

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17-40 and 42-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17-40 and 42-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-13,21-38,40,42,43,44 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Songer, et al.-'260 in view of Preissman-'465.

Songer discloses a crimp tube 36 crimped by a crimping tool having jaws, handles and crimping members with gaps therebetween when closed. A tensioner holds tension on a suture crimped into the lumen of the tube. Two crimp tubes are shown, one being the claimed crimp tube and the other being one of the set of crimp devices. The devices are disclosed as for use on the sternum or other bones (see col. 5 lines 23-29). However, a plurality of crimp devices is not disclosed.

It would have been obvious to have provided a set with more than two crimp tubes as it is nothing more than an obvious duplication of known parts, and would allow for the placement of a multitude of cables and associated crimp tubes along the sternum or other bone location. Additionally, it would allow for the possibility of still completing the procedure even in the event that a crimp tube either was not securely attached to either end of the cable or failed for any other reason.

Songer discloses the invention as claimed with the exception of the material of the crimp tube. Preissman discloses the use of a titanium crimp tube. It would have been obvious to have formed the crimp tube of Songer, out of titanium, as it is a biocompatible material used in surgical applications.

As for the specific limitations regarding the internal surface of the crimp tube having a bevel, and the specific widths and shapes of the crimping members, these are considered to be obvious design choices. One of skill in the art would know that a crimping tool commonly has a gap between the crimping surfaces when the handle is

Art Unit: 3731

completely closed to protect against over-crimping. The specifics of this distance would depend on the size of the crimp tube and the diameter of the suture or cable. Neither of these limitations is considered to be unobvious. Additionally, the inner surface widths of the crimping members is approximately half that of the prior art. However, as stated before, this gap is dependent on the diameters of the crimp tube and the cable or suture and one skilled in the art would have provided a crimping tool with proper specifications to apply a crimping tube to a cable or suture of a size requiring this gap. Forming the crimping members with a rectangular shape as opposed to a curved one would have no effect on the performance of the crimping procedure; the applicant did not state why such is critical to the invention, and therefore such a modification is again nothing more than an obvious design choice.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

Art Unit: 3731

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15,17-40 and 42-47 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6395010. Although the conflicting claims are not identical, they are not patentably distinct from each other because in many aspects, the application claims are merely broader in scope than those of the patent, with the exception of obvious modifications such as gap distances, inner widths or crimping member shapes. However, as noted in the previous 103 rejection, each of these limitations is considered to be obvious design choices. Therefore, the claims of the application are not patentably distinct from those of the patent and the claims are properly rejectable under obvious type double patenting.

### ***Response to Arguments***

Applicant's arguments filed 05-07-2007 have been fully considered but they are not persuasive.

The terminal disclaimer was not signed by an attorney of record and therefore it has not been entered and the double patenting rejection is sustained.

The previous arguments are re-iterated here as they directly pertain to the remarks by applicant in the last response.

The rejected claims using the term crimping device do not distinguish over the crimping tubes of Songer. Their use in assisting placing tension on the suture is not

Art Unit: 3731

persuasive in that the apparatus claims do not positively recite this limitation. The prior art crimp tubes could be used with pliers to apply tension to the suture.

Applicant argues that Songer only discloses a single crimp tube with a single cable or two crimp tubes with two cables. However, as clearly shown in fig. 8 during a surgical procedure, it would be common to use several cables, each with a crimp tube. Although only two of each is shown, it would be obvious that for some sternum closures or other bone repair procedures, more than two would be required. The examiner has previously stated and continues to be of the opinion, that it would have been obvious to have provided a "kit" or package with multiple cables (more than 2) and an equal number of crimp tubes in order to perform a complete procedure where more than two cables were needed. Once more than two cables and crimp tubes are placed in the kit, one or two of the tubes could be the claimed crimp tubes and others could be the claimed crimp devices.

It is irrelevant if Songer teaches away from a plurality of crimp tubes for the purpose of "attaching to 1<sup>st</sup> and 2<sup>nd</sup> portions of the suture". The examiner has provided motivation for providing a kit with the various claimed components. Once the plurality of crimping tubes are placed into the kit, one "could" place a plurality of crimp tubes on various locations of a single suture, and not destroy the manner in which the tensioning device operates. One could either thread several tubes onto the suture and could be crimped at locations along its' length. Or, one could choose not to cut the ends of the suture after a crimp tube was crimped onto the suture and the suture could be continually threaded about the spine and crimps placed every so many inches to keep

the suture tensioned in the spinal region. Either way, the examiner is not stating that it would have been obvious to place several crimp tubes along one suture (although this may indeed be obvious), rather the examiner is stating that once the kit was furnished with a plurality of these crimp tubes, one could use them on a single suture. The claim language is met because the limitation which the applicant is relying on for patentability is one of intended use, not one involving a structural difference between the applicant's device and the prior art.

Songer clearly shows that two cables and crimp tubes are commonly used in one procedure as noted in the figures. As Songer also details that the use of the device is not restricted to closure of sternums, the examiner's position is that in some situations, it might be necessary to provide 3 or even more cable/crimp tube sets for a proper closure or repair, depending on how extensive the damage is. Providing these in a set containing this plurality would have been obvious and a mere duplication of known parts. The fact that the individual components need to stay sterile prior to use is not a convincing argument as to why someone would not be motivated to provide a plurality of these sets in a "kit" or package. If need be, each individual component in the "kit" or "package" might be separately held in its own sterile compartment of a larger "kit" or package". The benefits of having additional components at hand and ready for use if needed in a procedure would outweigh any additional packaging requirements to ensure proper sterilization of the set components.



***Conclusion***


**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K. Dawson whose telephone number is 571-272-4694. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Glenn K Dawson  
Primary Examiner  
Art Unit 3731

Gkd  
18 July 2007